IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application No.: 10/600,177 Group: 1795

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Confirmation No.: 9752

For: METHOD AND APPARATUS FOR OPERATING AN AUTOMATED CAPILLARY ELECTROPHORESIS SYSTEM (AS AMENDED)

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APPEAL BRIEF

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This Appeal Brief is submitted pursuant to the Notice of Non-Compliant Appeal Brief dated October 7, 2009 received from the U.S. Patent and Trademark Office.

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I. REAL PARTY IN INTEREST

The real party in interest is Groton Biosystems, 85 Swanson Road, Suite 110, Boxborough, Massachusetts 01719. Groton Biosystems is the Assignee of the entire right, title and interest in the subject application, by virtue of an Assignment recorded on January 5, 2004 at Reel 014233, Frames 0700-0704.

II. RELATED APPEALS AND INTERFERENCES

Appellants, the undersigned Attorney, and the Assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-26 have been withdrawn. Claims 27 through 52 have been finally rejected, and a copy appears in the Claims Appendix, Section VIII of this Brief. Claims 27-52 appear as originally filed. Claims 27-52 are being appealed herein.

IV. STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the Final Rejection dated January 27, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 27

Claim 27 is an independent claim that claims an aspect of the present invention that relates to an apparatus for performing capillary electrophoresis. The apparatus includes an inlet chamber, capillary electrophoresis column, liquid source, and controller. The capillary electrophoresis column has one end fixedly coupled to the inlet chamber. The liquid source is coupled to the inlet chamber through an input valve to supply a liquid sample in a controlled manner to the inlet chamber. The controller is operatively coupled to the input valve and includes executable instructions to convert and execute operational input to control the valve for providing a sample of the liquid source to the capillary electrophoresis column.

Support for claim 27 may be found at least on page 5, line 27 through page 6, line 7; page 6, line 25 through page 7; and line 3 of Appellants' specification, in the Abstract, and at least in Fig. 16 as originally filed.

B. Claim 32

Claim 32 is a dependent claim that claims an aspect of the present invention that relates to an apparatus according to Claim 27 wherein the executable instructions convert the operational input by interpreting program instructions.

Support for claim 32 may be found at least on page 6, lines 8-9; page 7, lines 6-7 and 25-28; page 31, lines 10-12; and page 32, line 24 through page 33, line 14 of Appellants' specification, and at least in Fig. 16 as originally filed.

C. Claim 37

Claim 37 is a dependent claim that claims an aspect of the present invention that relates to an apparatus according to Claim 27 wherein the executable instructions include instructions to detect errors in the operational input.

Support for claim 37 may be found at least on page 6, lines 19-20; page 30, lines 19-20; and page 35, lines 10-14 of Appellants' specification, and at least in Fig. 16 as originally filed.

D. Claim 39

Claim 39 is an independent claim that claims an aspect of the present invention that relates to a method for performing capillary electrophoresis. The claimed method provides a liquid source in fluid communication via an inlet chamber to an end of a capillary electrophoresis column fixedly coupled to the inlet chamber. In response to converting and executing operational input, flow of the liquid source to the inlet chamber is controlled to provide a liquid sample in a controlled manner to the end of the capillary electrophoresis column.

Support for claim 39 may be found at least on page 5, line 27 through page 6, line 7; page 6, line 25 through page 7, line 3 of Appellants' specification, in the Abstract, and at least in Fig. 16 as originally filed.

E. Claim 45

Claim 45 is a dependent claim that claims an aspect of the present invention that relates to a method according to Claim 39 wherein converting the operational input includes interpreting program instructions.

Support for claim 45 may be found at least on page 6, lines 8-9; page 7, lines 6-7 and 25-28; page 31, lines 10-12; and page 32, line 24 through page 33, line 14 of Appellants' specification, and at least in Fig. 16 as originally filed.

F. Claim 50

Claim 50 is a dependent claim that claims an aspect of the present invention that relates to a method according to Claim 39 further including detecting errors in the operational input.

Support for claim 50 may be found at least on page 6, lines 19-20; page 30, lines 19-20; and page 35, lines 10-14 of Appellants' specification, and at least in Fig. 16 as originally filed.

G. Claim 52

Claim 52 is an independent claim that claims an aspect of the present invention that relates to an apparatus for performing capillary electrophoresis. The apparatus includes means for providing a liquid source in fluid communication via an inlet chamber to an end of a capillary electrophoresis column fixedly coupled to the inlet chamber. The apparatus also includes means for converting and executing operational input and responsively controlling flow of the liquid source to the inlet chamber to provide a liquid sample in a controlled manner to the end of the capillary electrophoresis column. The apparatus also includes means for performing the capillary electrophoresis.

Support for claim 52 may be found at least on page 5, line 27 through page 6, line 7; page 6, line 25 through page 7, line 3 of Appellants' specification, in the Abstract, and at least in Fig. 16 as originally filed. Claim 52 is written in means-plus-function form. The structure described in the specification that corresponds to the language of Claim 52 is as follows. The liquid sample source illustrated in Fig. 13, ref. no. 1301, inlet chamber illustrated in Fig. 13, ref. no. 1102, and capillary electrophoresis column illustrated in Fig. 13, ref. no. 1106 correspond to the means for providing a liquid source in fluid communication via an inlet chamber to an end of a capillary electrophoresis column fixedly coupled to the inlet chamber. The controller illustrated in Figs. 15 and 16, ref. no. 701/1330 corresponds to the means for converting and executing operational input and responsively controlling flow of the liquid source to the inlet chamber to

provide a liquid sample in a controlled manner to the end of the capillary electrophoresis column. The valves illustrated in Fig. 13, ref. nos. 1304, 1308, 1310, 1312, 1322, 1324, and 1326, pumps illustrated in Fig. 13, ref. nos. 1302 and 1320, optional electrophoresis power supply illustrated in Fig. 13, ref. no. 1108, and optional detector illustrated in Fig. 13, ref. no. 1110 correspond to the means for performing the capillary electrophoresis.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether Claims 27 and 52 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by Virtanen *et al.* (U.S. Pat. No. 6,402,919, hereinafter "Virtanen");

whether Claims 39, 40, 49, and 51 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen;

whether Claims 28-34, 36, and 41-46 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen in view of Nikiforov *et al.* (U.S. Pat. No. 7,060,171, hereinafter "Nikiforov");

whether Claims 34 and 35 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen in view of Nikiforov, and further in view of Li *et al.* (U.S. Pat. No. 6,375, 819, hereinafter "Li");

whether Claim 37 is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen in view of Nikiforov, and further in view of Sarrine (U.S. Pat. No. 5,147,522, hereinafter "Sarrine");

whether Claim 38 is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen in view of Nikiforov, and further in view of Karger *et al.* (U.S. Pat. No. 5,348,633, hereinafter "Karger") or Sarme *et al.* (U.S. Pat. No. 7,261,801, hereinafter "Sarme");

whether Claims 47 and 48 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen in view of Li; and

whether Claim 50 is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen in view of Sarrine.

VII. ARGUMENT

A. The Claimed Invention in Context

Automation can be applied to the preparation of macromolecules and electrophoresis in the analysis of the prepared macromolecules. In this automation, executable instructions,

typically in the form of software or firmware, control processes through the operation of valves, pumps, heater elements, cooling elements, pressure sensors, and other elements employed to perform functions used to prepare the macromolecule.

Because these automated processes are applied to biological materials, a regulatory body, such as the Food and Drug Administration (FDA), may provide oversight for the manufacturing, operation, or output of the system. In other words, since the output of the system (i.e., macromolecules) may be used by pharmaceutical companies in production of ingestable products by humans and/or animals, a government agency may oversee such a system, which includes the executable instructions used to operate and control the system. Thus, not only must the executable instructions be capable of operating the system in a manner consistent with production of the macromolecules according to a given set of specifications, they may also be required to adhere to certain regulations, in which case validation and approval is sought from the regulatory body providing the oversight by the manufacturer and/or end user.

Accordingly, one embodiment of the present invention is employed in a system used to prepare a macromolecule sample. The system includes a hydraulic subsystem designed to separate a macromolecule from a mixture that also includes larger and smaller components. A controller is employed to control the hydraulic subsystem in a manner adapted for preparing the macromolecule sample. The controller includes executable instructions, such as compiled software (i.e., software that is unchangeable by the end user), that has instructions to convert and execute operational input to control the hydraulic subsystem. The executable instructions may be unchangeable and conform to a known industry standard, such as American National Standards Institute (ANSI) (e.g., ANSI 'C' programming language). The operational input may include instructions, such as declarative software instructions, that are interpreted by the compiled software.

An advantage for using the method described above for distributing the system to a customer is that the customer can customize the operational input independent of compiled software following the validation and approval of the system with the executable instructions, since the executable instructions "convert and execute operational input" (Claim 27; emphasis added). Notably, the claimed invention converts operational input prior to execution. The operational input may be program instructions, optionally plain-english like, that are interpreted by the executable instructions to cause the system to prepare or analyze, for example, macromolecules in a manner consistent with desired characteristics given a mixture including

smaller and larger components in the mixture. In other words, converting operational input as in the claimed invention may include "interpreting program instructions" (Claim 32).

Another advantage is that the customer can later obtain approval from a government agency, such as the Food and Drug Administration (FDA) or Department of Defense (DOD), for the operational input without having to repeat the validation and approval processes for the executable instructions. This reduces the customer's costs for revalidation and further approval. Furthermore, independent validation and approval of the executable instructions and operational input reduces long-term costs incurred by the manufacturer of the system since the manufacturer will not have to be involved with any later validation and approval processes following customizing or modification of the operational input by the customer.

By having a clear demarcation, the manufacturer may guarantee continued approval by the regulatory body of the system with the executable instructions regardless of changes to the operational input. One way the manufacturer may guarantee this is by validating the executable instructions following testing of the system for a range of operational inputs reasonably or unreasonably expected to be applied by the customer to the system to perform its intended use, such as preparing or analyzing macromolecules.

B. Virtanen Does Not Disclose All the Elements of Claims 27 and 52.

The Examiner asserted, in the final rejection under 35 U.S.C. § 102(b), that Virtanen discloses all the elements of Claim 27. Elements of Claim 27 of interest for the instant appeal include the following:

> a controller operatively coupled to the input valve and including executable instructions to convert and execute operational input to control the valve for providing a sample of the liquid source to the capillary electrophoresis column.

In the non-final rejection of August 15, 2008, the Examiner stated that the foregoing elements related to the controller are implied by Virtanen at col. 3, lines 36-37, which states, "Operation of the entire apparatus can be controlled by means of a micro-processor." The Examiner also cited Virtanen col. 3, line 51 through col. 4, line 39, directed to an embodiment of Virtanen involving a particular technique of injecting (feeding) a sample; this section of Virtanen discloses controlling and modifying certain parameters to introduce many different ways of sample feeding and to implement initial and boundary conditions for various electrophoresis applications. However, as for actual implementation details related to control via a

microprocessor, Virtanen discloses only the single sentence stated above ("Operation of the entire apparatus can be controlled by means of a micro-processor").

MPEP 2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." The non-final Office Action stated that the foregoing elements of Claim 27 related to the controller are "implied" by Virtanen's sentence, "Operation of the entire apparatus can be controlled by means of a micro-processor." In the final Office Action, the Examiner maintained the anticipation rejection of Claim 27 from the non-final Office Action and stated that Virtanen implies associated electronic means for converting operational input (emphasis in original). The Examiner further stated, "other conventional associated electronic components are necessary in conjunction with the microprocessor for operation of the entire apparatus of Virtanen." Thus, both non-final and final Office Actions acknowledged that Virtanen does not expressly teach "operational input" of Appellants' Claim 27.

Appellants will first show below that the foregoing elements of Claim 27 are not inherently described and then will show that one of ordinary skill in the art would not have drawn the implication mentioned above in the Office Action, i.e., the reference alone would not have enabled one of ordinary skill in the art to arrive at Appellants' Claim 27. The following arguments were previously presented in the Appellants' Reply After Final Rejection.

MPEP 2121 states:

> A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention ...(*Impax Labs. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383, 81 USPQ 2d 1001, 1013 (Fed. Cir. 2006)

The CAFC decision cited in the foregoing MPEP section states, "Prior art is not enabling so as to be anticipating if it does not enable a person of ordinary skill in the art to carry out the invention." Furthermore, in an opinion citing *Impax Labs Inc.*, the CAFC stated in *In re Martin Gleave and Maxim Signaevsky* (CAFC 2008-1453):

> A reference is anticipatory under § 102(b) when it satisfies particular requirements. ... [T]he reference must "enable one of ordinary skill in the art to make the invention without undue experimentation."

1. Virtanen does not inherently describe the elements of Claim 27 that are not expressly described.

The non-final Office Action stated that Virtanen discloses the foregoing elements of Claim 27 related to converting and executing operational input impliedly based on the single sentence "Operation of [Virtanen's] entire apparatus can be controlled by means of a micro-processor." The final Office Action states that the foregoing statement of Virtanen implies various intermediate level processing between the stage of user input and the binary code handled by the microprocessor.

However, Appellants' claimed invention as in Claim 27 exceeds the scope of what would be found inherently at an intermediate stage of processing in a controller for an apparatus such as Virtanen's. Virtanen's apparatus, in order to be controlled by a microprocessor, would undoubtedly require additional electronic components than just a microprocessor. However, Virtanen, by providing only a single sentence directed to such a controller, leaves unclear exactly which additional components would be needed, or for what specific functionality. It is improper to draw from Virtanen's single broad statement an implication that Virtanen teaches "a controller ... including executable instructions to convert and execute operational input" as in Appellants' Claim 27 (emphasis added). An example of Appellants' "operational input" may be in the form of an English-like pseudolanguage, as seen in Appellants' specification as originally filed at page 32, lines 1-20). At most, a standard (conventional) implementation according to the principles of automatic control (e.g., using a microprocessor) would have enabled one of ordinary skill in the art to perform execution of input data. Input data is generally understood to be quantitative digital numerical or boolean representation of a state of an element (e.g., sensor measurements (e.g., 3.486), pump state (open/closed), valve state (open/closed)), but input data is quite different from Appellants' "operational input" in the form of an English-like pseudolanguage, an example of which can be seen in Appellants' specification as originally filed at page 32, lines 1-20).

According to the website http://www.dictionary.com, the word "inherent" means "existing in someone or something as a permanent and inseparable element, quality, or attribute" (emphasis added). Conversion of operational input as in Applicant's Claim 27 is not inherent to a controller implementation of Virtanen's apparatus, since such conversion is not an inseparable element of the implementation. One may implement a controller that performs standard controlling functions (e.g., for automation) without converting and executing operational input; in fact, an implementation without such elements would be standard practice. In response to the final Office Action, Appellants submitted a Declaration under 37 C.F.R. § 1.132, by one of ordinary skill the in the art, that describes such a standard ("turnkey") implementation (copy

provided in the attached Evidence Appendix). Absent any other guidance in Virtanen, it is improper to conclude that sophisticated intermediate level processing as in Appellant's claimed invention would be inherent to Virtanen.

The Examiner also stated in the Final Office Action that Virtanen teaches adjusting, controlling, and modifying certain parameters. The Examiner referred to these actions in Virtanen as "operations" (emphasis in Office Action) and further refers to Virtanen's Claim 5, which recites "pumps ... operatively connected with ... solution reservoirs" (emphasis in Office Action). The Office Action apparently construes such teachings of operations and operatively connected pumps as equivalent to Appellants' "operational input" as in Claim 27. However, the mere use of the word "operatively" by Virtanen, in conjunction with "adjusting," "controlling," and "modifying," does not mean that Virtanen teaches "convert[ing] and execut[ing] operational input" as in Claim 27 (emphasis added).

At most, disclosure by Virtanen of adjusting, controlling, and modifying teaches an ability on the part of a user to vary input parameters. Such teaching still refers to turnkey systems in which a user may request a particular level (thus modifying a parameter) and then initiate operation (e.g., by pressing a button). Such disclosure by Virtanen includes, at most, execution of operational input, but is patentably distinct from "convert[ing] and execut[ing] operational input" (emphasis added), which involves more sophisticated processing at an intermediate stage than Virtanen teaches or suggests.

2. Virtanen does not enable a person of ordinary skill in the art to make Appellants' claimed invention.

The implications described above (i.e., that Virtanen would have such additional elements regarding Appellants' Claim 27 that are not expressly disclosed) are not clear to a chemist, who is the relevant person of ordinary skill in the art of capillary electrophoresis (the relevant art in the context of embodiments of Appellants' claimed invention). In other words, although the Examiner stated in the final Office Action that Virtanen implies existence and functionality of intermediate processing components, a person of ordinary skill in the art of capillary electrophoresis would not be skilled in electronic devices and electronic processing and would not have been enabled, based on Virtanen alone, to design a system to "convert and execute operational input" as in Claim 27 (emphasis added).

A Declaration under 37 C.F.R. § 1.132 submitted on May 27, 2009 and submitted as a copy herewith in the Evidence Appendix (Section IX) provides further support for this argument. The Declaration states that a person of ordinary skill would have sought (prior to the time of Appellants' claimed invention) a turnkey solution that would lack elements of Claim 27, e.g., "executable instructions to convert and execute operational input."

The Examiner stated in the Advisory Action dated June 11, 2009 that Virtanen does disclose conversion and execution of operational input as in Claim 27. Examiner offered the following sentences in support:

> Virtanen discloses setting initial and boundary conditions for certain parameters, yet arbitrarily modifying test conditions during a run. See col. 02:29-44. It is unllikey (*sic*) that Virtanen contemplated a person constantly making measurements or reading meters, making calculations, and twirling dials to ensure a successful electrophoresis run. It is more likely that Virtanen contemplated a software (*sic*) that allows the user to set some initial and boundary conditions and based on these conditions and feedback input from the apparatus on operating conditions and parameter values to make adjsutments (*sic*) accordingly.

First of all, the foregoing views constitute speculation by the Examiner and cannot reasonably be inferred from the Virtanen's single sentence directed to implementation using a microprocessor. Furthermore, even the processing/implementation that the Examiner states that Virtanen is "likely" to have contemplated differs patentably from Appellants' Claim 27, since allowing a user to set initial/boundary conditions and vary subsequent processing based on feedback is patentably distinct from "converting and executing operational input."

In the Advisory Action, the Examiner further referred to the following disclosure from Virtanen's background section: "capillary electrophoresis can be readily automated" (Virtanen col. 1, lines 34-35). However, Appellants are not contending that automation of capillary electrophoresis in general was not known prior to Appellants' claimed invention, but rather that such conventional (e.g., turnkey-style) automation is patentably different from Appellants' claimed invention. The Declaration under 37 C.F.R. § 1.132 explains how one of ordinary skill in the art would have "readily automated" capillary electrophoresis prior to Appellants' claimed invention. The Examiner discounted the Declaration under 37 C.F.R. § 1.132 because it is allegedly "partly at variance with a fair reading of Virtanen." However, the Declarant is a person of ordinary skill in the art, who has explained how a person of ordinary skill would have interpreted/used Virtanen, and the Examiner has only offered speculation (regarding what is likely or unlikely for Virtanen to have contemplated) in an opposing view. The Declaration is not in variance with "a fair reading" of Virtanen, as the Examiner has stated, but, rather, in variance with the Examiner's (overly broad, speculative) reading thereof.

In view of the foregoing statements, Virtanen does not disclose all the elements of Claim 27 and, consequently, does not anticipate the claim. Claim 52 recites similar elements as Claim 27 and is not anticipated for at least the same reasons as presented above.

C. Virtanen Does Not Render Obvious Claim 39.

Claim 39 recites similar elements as Claim 52; Claim 52 is essentially a "means plus function" version of Claim 39. Notably, Claim 39 was rejected based on obviousness (not anticipation) over Virtanen, which is inconsistent with the anticipation rejection of Claim 52. In fact, in the non-final rejection of Claim 39, the Examiner conceded that Virtanen does not specifically mention "in response to converting and executing operational input, controlling the flow of the liquid source to the inlet chamber to provide a liquid sample in a controlled manner to the end of the capillary electrophoresis column." That concession alone provides further weight to the impropriety of the anticipation rejection of Claims 27 and 52, discussed above. In any event, one of ordinary skill in the art would not have found it obvious to modify Virtanen to arrive at Appellants' Claim 39, because such a person would have sought a turnkey-style automation system instead, as discussed above (and as presented in the Declaration under 37 C.F.R. § 1.132). Therefore, Virtanen does not make obvious Claim 39.

Dependent claims 28-38 and 40-51 inherit the foregoing patentably distinguishing elements from respective base claims 27 and 39 and should be allowable for at least the same

reasons as presented above, since the secondary reference(s) introduced against those dependent claims (Nikiforov, Li, Sarrine, Karger and/or Sarme) do not cure the deficiency of Virtanen regarding the independent claims.

D. Virtanen and Nikiforov do not Render Obvious Claim 32.

Furthermore, Appellants respectfully submit Claim 32 is additionally patentable at least for reciting the following elements: "The apparatus according to Claim 27 wherein the executable instructions convert the operational input by interpreting program instructions."

The Examiner conceded in the non-final Office Action that Virtanen does not disclose "convert[ing] the operational input by interpreting program instructions." The Examiner stated that it would have been obvious to perform the missing elements. The Examiner stated:

> it should be noted ... that as shown by Nikiforov it was known at the time of the invention to use an appropriately programmed computer to instruct a controller in a microchannel electrophoresis system. See col. 08:05-14.

Such teaching of Nikiforov, in conjunction with Virtanen, would not have enabled one of ordinary skill in the art to arrive at Claim 32. The cited portion of Nikiforov states:

> [Nikiforov's] system also includes a detector 404 as well as a computer or processor 406 that is operably coupled to both the detector 404 and the controller 402 . The computer typically includes appropriate programming to receive user input information and transfer that information into instructions for the flow controller. The computer also typically receives the data from the detector and manages that data into a user understandable presentation.

The foregoing portion of Nikforov does not teach converting operational input at all, much less "convert[ing] operational input by interpreting program instructions." Rather, the cited passage discloses control of flow (e.g., fluid flow) using a controller and a computer or processor. Such control refers to conventional control techniques that one of ordinary skill in the art (of electrophoresis) would have sought, e.g., turnkey-style execution of embedded instructions using a microcontroller. The "appropriate programming" disclosed by Nikiforov further refers to conventional techniques along the lines of those discussed above in the context of Virtanen and the Declaration under 37 C.F.R. § 1.132 (although the Declaration does not refer to Nikiforov explicitly).

The Examiner stated in the final Office Action that interpreters were known at the time of Appellants' claimed invention, and the Examiner introduced a Wikipedia article as a reference to that effect. However, as Appellants stated previously in the Reply After Final Rejection, even

such disclosure of interpreters does not lead to a proper obviousness determination. MPEP 2143 states that the Graham factors relevant to an obviousness determination (e.g., regarding obviousness to combine references) must be considered in the context of a person of ordinary skill in the art. On a related note, MPEP 2141.03 states:

> The examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. (emphasis added)

Based on the foregoing MPEP sections (2143 and 2141.03), there is lack of motivation to combine Virtanen and Nikiforov (and/or the Wikipedia reference, since the Examiner introduced that reference for interpreters) to arrive at Claim 32. As stated previously, the relevant person of ordinary skill for the present inquiry is skilled in the art of capillary electrophoresis. Such a person would not have turned to teachings regarding interpreters to apply such teachings for use in a capillary electrophoresis system to implement a sophisticated intermediate layer of processing between an end-user and a microcontroller.

Instead, such a person would have sought a conventional automation technique, e.g., involving a microprocessor, as suggested by Virtanen. Even if Nikiforov were combined with Virtanen, Nikiforov teaches conventional automation/programming solutions as well, as shown above in the cited passage of Nikiforov. Such a "turnkey" solution for automation would have enabled an end user (a chemist skilled in capillary electrophoresis but not in computer programming, computer systems, or automated systems) to operate a capillary electrophoresis system by turning a key, pressing a button, or performing other simple steps to operate valves and equipment. Such a technique might have enabled modifying parameters in a simple way (as in Virtanen) but would not have included sophisticated intermediate processing that includes an interpreted language (as in the Wikipedia reference). In other words, the art of interpreted languages is "remote" with respect to capillary electrophoresis in the context of MPEP 2141.03, and it would not have been obvious to one of ordinary skill in the art (of capillary electrophoresis) to combine Virtanen and Nikiforov/Wikipedia to arrive at Claim 32.

Similar arguments apply for Claim 45, which also recites interpreting program instructions.

E. Virtanen, Nikiforov and Sarrine Do Not Render Obvious Claim 37.

Furthermore, Claim 37 is additionally patentable at least for reciting "detect[ing] errors in the operational input." Sarrine was introduced as a secondary reference in the obviousness

rejection of this claim. The non-final Office Action states, at page 19, line 14, that Sarrine discloses an automatic electrophoresis apparatus and control having "an input signal regarding the alignment of the sample source. The automation means is configured to detect an error in this signal." However, Sarrine's error detection of an input signal is patentably distinct from error detection of "operational input" as in Appellants' Claim 37. Sarrine's error detection is of the kind conventionally found in automation systems, e.g., turnkey systems as in the discussion above about a person of ordinary skill being a chemist. The Advisory Action did not discuss the foregoing arguments previously presented by Appellants in the Reply After Final Rejection.

Similar arguments apply for Claim 50, which also recites detecting errors in operational input.

In view of the foregoing, Appellants respectfully request the Board to rule in favor of a withdrawal of the rejection of Claims 27 through 52 under 35 U.S.C. §102(b) and the rejection of Claims 28-51 35 U.S.C. §103(a) and recommend the application be allowed to pass to issue.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. (Withdrawn) An apparatus for preparing a macromolecule sample, comprising:

a hydraulic system designed to separate a macromolecule from a mixture that also includes larger and smaller components; and

a controller operably coupled to the hydraulic system and including executable instructions to convert and execute operational input to

control the hydraulic system in a manner for preparing the macromolecule sample.

2. (Withdrawn) The apparatus according to Claim 1 wherein the executable instructions are compiled software.

3. (Withdrawn) The apparatus according to Claim 1 wherein the executable instructions are unchangeable.

4. (Withdrawn) The apparatus according to Claim 1 wherein the executable instructions conform to a known industry standard.

5. (Withdrawn) The apparatus according to Claim 1 wherein the operational input includes declarative software instructions.

6. (Withdrawn) The apparatus according to Claim 1 wherein the executable instructions include instructions to interpret program instructions.

7. (Withdrawn) The apparatus according to Claim 1 wherein the operational input is modifiable independent of the executable instructions.

8. (Withdrawn) The apparatus according to Claim 1 wherein the controller includes an interface to receive the operational input from an external system.

9. (Withdrawn) The apparatus according to Claim 8 wherein the external system is coupled to the interface via a network.

10. (Withdrawn) The apparatus according to Claim 1 wherein:

the hydraulic system includes multiple devices addressable by the controller; and

the executable instructions include correspondence between predetermined indicators in the operational input and the multiple devices.

11. (Withdrawn) The apparatus according to Claim 1 wherein the executable instructions include instructions to detect errors in the operational input.

12. (Withdrawn) The apparatus according to Claim 1 wherein the hydraulic system includes:

at least one rough filter and at least one fine filter; and

a pump and at least one valve.

13. (Withdrawn) A method for preparing a macromolecule sample, comprising:

separating a macromolecule from a mixture that also includes larger and smaller components; and

converting and executing operational input to control the separating of the macromolecule in a manner for preparing the macromolecule sample.

14. (Withdrawn) The method according to Claim 13 wherein converting and executing the operational input includes executing executable instructions.

15. (Withdrawn) The method according to Claim 14 wherein the executable instructions are compiled software.

16. (Withdrawn) The method according to Claim 14 wherein the executable instructions are unchangeable.

17. (Withdrawn) The method according to Claim 14 wherein the executable instructions conform to a known industry standard.

18. (Withdrawn) The method according to Claim 13 wherein the operational input includes declarative software instructions.

19. (Withdrawn) The method according to Claim 13 wherein converting the operational input includes interpreting program instructions.

20. (Withdrawn) The method according to Claim 13 wherein the converting and executing is performed by executable instructions and the operational input is modifiable independent of the executable instructions.

21. (Withdrawn) The method according to Claim 13 further including receiving the operational input from an external system.

22. (Withdrawn) The method according to Claim 21 wherein receiving the operational input includes communicating across a network.

23. (Withdrawn) The method according to Claim 13 wherein converting and executing the operational input includes determining correspondence between predetermined indicators in the operational input and devices used for separating the macromolecule from the mixture.

24. (Withdrawn) The method according to Claim 13 further including detecting errors in the operational input.

25. (Withdrawn) The method according to Claim 13 wherein the separating includes (i) rough and fine filtering the mixture and (ii) operating a pump and at least one valve to cause pressure differentials across the filters.

26. (Withdrawn) An apparatus for preparing a macromolecule sample, comprising:

means for separating a macromolecule from a mixture also including larger and smaller components; and

means for converting and executing operational input for controlling the means for separating the macromolecule from the mixture.

27. (Original) An apparatus for performing capillary electrophoresis, comprising:

an inlet chamber;

a capillary electrophoresis column with one end fixedly coupled to the inlet chamber;

a liquid source coupled to the inlet chamber through an input valve to supply a liquid sample in a controlled manner to the inlet chamber; and

a controller operatively coupled to the input valve and including executable instructions to convert and execute operational input to control the valve for providing a sample of the liquid source to the capillary electrophoresis column.

28. (Original) The apparatus according to Claim 27 wherein the executable instructions are compiled software.

29. (Original) The apparatus according to Claim 27 wherein the executable instructions are unchangeable.

30. (Original) The apparatus according to Claim 27 wherein the executable instructions conform to a known industry standard.

31. (Original) The apparatus according to Claim 27 wherein the operational input includes declarative software instructions.

32. (Original) The apparatus according to Claim 27 wherein the executable instructions convert the operational input by interpreting program instructions.

33. (Original) The apparatus according to Claim 27 wherein the operational input is modifiable independent of the executable instructions.

34. (Original) The apparatus according to Claim 27 wherein the controller includes an interface to receive the operational input from an external system.

35. (Original) The apparatus according to Claim 34 wherein the external system is coupled to the controller via a network.

36. (Original) The apparatus according to Claim 27 wherein the executable instructions include correspondence between predetermined indicators in the operational input and the input valve.

37. (Original) The apparatus according to Claim 27 wherein the executable instructions include instructions to detect errors in the operational input.

38. (Original) The apparatus according to Claim 27 wherein the inlet chamber is coupled to a hydraulic system including rough and fine filters, a pump, and at least one valve.

39. (Original) A method for performing capillary electrophoresis comprising:

providing a liquid source in fluid communication via an inlet chamber to an end of a capillary electrophoresis column fixedly coupled to the inlet chamber; and

in response to converting and executing operational input, controlling flow of the liquid source to the inlet chamber to provide a liquid sample in a controlled manner to the end of the capillary electrophoresis column.

40. (Original) The method according to Claim 39 wherein converting and executing the operational input includes executing executable instructions.

41. (Original) The method according to Claim 40 wherein the executable instructions are compiled software.

42. (Original) The method according to Claim 40 wherein the executable instructions are unchangeable.

43. (Original) The method according to Claim 40 wherein the executable instructions conform to a known industry standard.

44. (Original) The method according to Claim 39 wherein the operational input includes declarative software instructions.

45. (Original) The method according to Claim 39 wherein converting the operational input includes interpreting program instructions.

46. (Original) The method according to Claim 39 wherein the converting and executing is performed by executable instructions, and the operational input is modifiable independent of the executable instructions.

47. (Original) The method according to Claim 39 wherein converting and executing operational input includes receiving the operational input from an external system.

48. (Original) The method according to Claim 47 wherein receiving the operational input includes interfacing to the external system via a network.

49. (Original) The method according to Claim 39 further including determining correspondence between predetermined indicators in the operational input and a device used to control the flow of the liquid source.

50. (Original) The method according to Claim 39 further including detecting errors in the operational input.

51. (Original) The method according to Claim 39 further including operating a hydraulic system producing the liquid source.

52. (Original) An apparatus for performing capillary electrophoresis comprising:

means for providing a liquid source in fluid communication via an inlet chamber to an end of a capillary electrophoresis column fixedly coupled to the inlet chamber;

means for converting and executing operational input and responsively controlling flow of the liquid source to the inlet chamber to provide a liquid sample in a controlled manner to the end of the capillary electrophoresis column; and

means for performing the capillary electrophoresis.

IX. EVIDENCE APPENDIX

(1) Declaration under 37 C.F.R. § 1.132 by Dr. George Barringer filed on May 27, 2009

X. RELATED PROCEEDINGS APPENDIX

None.